UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,516	02/06/2002	Gillian Rosemary Bullock	4-30755B	4159

1095 7590 07/11/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	15

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,516	BULLOCK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/468,663* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed April 21, 2003 have been received and entered into the application.

1. Applicants' arguments filed April 21, 2003 have been fully considered but they are not persuasive. Applicants argue that Wagner does not explicitly teach a valsartan composition comprising more than 30% microcrystalline cellulose. However, this is not persuasive because as also pointed out by the Applicants' that the binders including microcrystalline cellulose as being from 10 to 45% is well taught by Wagner which encompasses Applicants' amount of microcrystalline cellulose present more than 30%. Applicants further argue that as originally filled, on page 24, lines 13-15, after exhaustive testing, applicants determined that increasing the amount of microcrystalline cellulose to greater than 30%, improves the bioavailability of solid formulation. However, this is not persuasive because alleged "improvement" of the bioavailability of solid formulation by increasing the amount of microcrystalline cellulose to greater than 30% is not established since there is no comparative data to support the allegation. Therefore, one of ordinary skill in the art would formulate valsartan composition comprising microcrystalline cellulose as being from 10 to 45% which includes Applicants amount as being above 30% as taught by Wagner.

It is suggested, to advance the prosecution of the subject application, that a side-by-side comparison of improvement of bioavailability data be performed and results submitted per Rule 1.132 for review by the Patent Office.

In view of the above Office Action of October 22, 2002 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7-12 and 17-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Wagner et al. (WO 97/49394).

Wagner et al. on the abstract, page 2, lines 1-6, line 10-12, lines 19-22, page 4, line 12, page 12, lines 1-4, page 14, Example 1 and page 15, Example 2, teach Applicants' solid oral dosage form comprising valsartan set forth in claims 7-12 and 17-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) in view of Pool et al.(1998).

Wagner et al. on page 12, lines 1-4, page 14, Example 1 and page 15, Example 2, teach Applicants' solid oral dosage form comprising valsartan set forth in claim 13 and 8.

Wagner et al. also on page 4, lines 22-23, and page 7, lines 20-23 teach dosage range of crospovidone in Wagner's composition is preferably present in an amounts of from 10 to 20 %, e.g. about 13% by weight.

Wagner et al. on page 2, lines 15-22 teach preferred dosage range of valsartan as 10 to 250mg consists entirely of valsartan and the effective amounts can be easily determined by person skilled in the art by routine experimentation and with no undue burden.

Pool et al. on the abstract teach the various dosage amounts of varsartan including the dose up to 320 mg administered once daily for treatment of hypertension.

Pool et al. also teach on the abstract that valsartan provides a clear increase in blood-pressure-lowering efficacy with increasing dose up to 320mg or the dose-responsive antihypertensive efficacy across the therapeutic dose range, which is demonstrated by the data.

The difference between primary reference and Applicants' claimed invention is dosage range of valsartan more than 250mg and up to 360mg set forth in claim 14 and the crospovidone content less than or equal to 13%. However, the skill artisan would have been motivated to modify the amount of crospovidone content with reasonable expectation of success, since Wagner et al. teach that crospovidone is preferably present in any amount of from 10 to 20%.

Furthermore, the Pool's data demonstrate a clear increase in blood-pressure-lowering efficacy with increasing dose up to 320mg of valsartan. Therefore, the skill artisan would be motivated with reasonable expectation of success to formulate Wagner's composition up to 320mg or higher amounts of Valsartan since as demonstrated by Pool's data, there is a clear increase in blood-pressure-lowering efficacy with increasing dose of valsartan.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
July 9, 2003